

REMARKS

I. Status of the Claims

Claims 1-17 are pending in the application. Claim 11 is withdrawn pursuant to an election of species requirement, and thus claims 1-10 and 12-17 are under consideration and stand rejected under 35 U.S.C. §102 and §103. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §102

Claims 1, 3, 7, 9, 10, 14, 16 and 17 stand rejected as anticipated by Zoha *et al.* Applicants traverse, but in the interest of advancing the prosecution, the elements of claim 5 have been introduced into claim 1, and the elements of claim 12 have been introduced into claim 3. As neither claim 5 nor claim 12 were rejected under §102, it is believed that the amendments overcome the rejection as all of the remaining claims depend from claim 1 or claim 3. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

III. Rejections Under 35 U.S.C. §103

Claims 1-4 and 8 stand rejected over Zoha *et al.* in view of Schobell *et al.* Applicants submit that the rejection is overcome by the amendments introducing the limitations of claim 5 and 12 into claims 1 and 3, respectively, referred to above. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Claims 1-4, 6, 8, 13 and 15 stand rejected over Zoha *et al.* in view of Cros *et al.* Applicants submit that the rejection is overcome by the amendments introducing the limitations

of claim 5 and 12 into claims 1 and 3, respectively, referred to above. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Claims 1, 3, 5 and 12 stand rejected over Zoha *et al.* in view of Nilsen *et al.* The examiner argues that though Zoha *et al.* only mentions latex particles as “macromolecules,” it was “known in the art at the time ... the claimed invention was made at taught by Nilsen *et al.* who teaches novel classes of reagents for detecting target nucleic acid reagents comprising nucleic acid attached to a bead, ... thus teaching macromolecules are nucleic acids.” Applicants traverse.

The examiner states that Zoha, in FIG. 3B, discloses a latex bead to which analytes are abound, and which can be used in a competitive binding format where binding partners for the analytes are located on a substrate. Regardless of whether the latex bead would be considered a macromolecule, it is certainly not one of the macromolecules now recited in the instant claims. In contrast to Zoha, Nilsen’s beads are composed of DNA matrices, and thus the examiner is right in stating that the secondary references teaches the use of nucleic acids as macromolecules in a detection system. However, the examiner’s statement “the nucleic acids are attached to the bead” is incorrect. The beads are *composed* of DNA matrices, but no DNA is “attached” to a bead. Moreover, the analyte to be detected is *not* coupled to Nilsen’s bead as in applicants’ claims and in the disclosure of Zoha. Rather, the bead is *composed* of a binding partner of the analyte – see FIG. 5, where the beads are comprised of negative strands and the positive strand target cross-links the two beads.

The question posed by the examiner’s combination of Zoha and Nilsen is whether there was motivation to substitute the latex bead of Zoha with the nucleic acid beads of Nilsen.

Applicants submit that the examiner has not established, even in a post-KSR environment, that motivation exists to combine these references as posited, for the reasons set forth below.

First, like applicants' macromolecule, Zoha's bead is coated with *analyte*, not the analyte's binding partner. In contrast, Nilsen's nucleic acids on the surface of the beads are used directly for detecting specific nucleic acid sequences, wherein the bead's nucleic acids are complementary to the nucleic acids sequence to be detected (see Nilsen, col. 15, lines 42-64). In the presently claimed invention, a nucleic acid macromolecule is used only as a platform for the coupled analytes on the one hand, and the fluorescence-dye on the other, and no nucleic acid sequences are detected, *e.g.*, a hormone, an antibody, an antibiotic, a doping agent, a vitamin, a steroid, a pesticide, a psychoactive drug, or a potential biological weapon are now recited in the claims (see page 6 of the specification for support). Notably, nucleic acids are *not* among this list. Thus, there is no reason that the skilled artisan would turn to the nucleic acid "bead" teachings of Nilsen when presented with the opportunity to improve on the methods of Zoha.

Second, it is argued that the Nilsen indicates that making a bead comprising numerous copies of the binding partner will reduce background and increase sensitivity. Once again, that is *not* what applicants here have done – their beads are not *composed* of binding partner, but are *coated with analyte*. In any event, the reason for the benefit of less background, as taught by Nilsen, is that binding of the probe to non-homologous DNA sequences is likely to be minimal since there is no room in the surface DNA layer to saturate all available hybridization sites much less whole beads (see Nilsen, column 18, lines 18 - 31). However, this advantage of less background signal is achieved specifically with regard to Southern hybridization assay detecting nucleic acid analytes. As discussed above, this is *not* an aspect of the claimed invention as

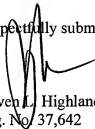
presented for reconsideration. Thus, whatever perceived advantage Nilsen might present for nucleic acids is not at all relevant for the instant claims. Consequently, in view of the teaching of Zoha, the skilled person did not have any motivation to use nucleic acids as the recited macromolecules instead of the latex particles of Zoha..

In light of the foregoing, applicants respectfully submit that the asserted reasons to combine Zoha with Nilsen crumble upon any kind of scrutiny, and maintenance of the combination is therefore improper. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

IV. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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